INTEGRA NEUROSCIENCES™

Single-Parameter Monitor
Model SPM-1
Technical Manual

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1.1 Proprietary Information

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1.2 Authorised Service

This manual is intended for use by biomedical personnel to perform operational checks. Any adjustments or procedures that exceed the scope of this manual should be referred to Integra NeuroSciences. Please note that operational tests performed internally by Integra NeuroSciences utilise custom test fixtures that are proprietary in nature. Therefore, there may be a discrepancy in the test results obtained by an outside party attempting to reproduce our exact product specifications and test methods.

Integra NeuroSciences does not condone or approve of service activity on its products by anyone other than Integra NeuroSciences personnel; and Integra NeuroSciences is not responsible for any unauthorised repairs.

1.3 Definition of Warning, Caution and Note

Warning Describes situations that could result in potentially serious outcomes (death, injury, or adverse event) to the patient or user.

Caution Advises against actions or situations that could damage equipment.

Note Indicates points of particular interest for more efficient and convenient operation.

1.4 Safety Considerations

Warning Risk of explosion if used in the presence of flammable anesthetics.

Warning Always unplug the SPM-1 from AC power before any major cleaning.

Caution Never use spraying fluids or fluid jets to clean the SPM-1. Clean outer surfaces by wiping with a soft, moist cloth that is slightly moist but not dripping with warm water, or a general non-staining chemical disinfectant. Do not use solvents or cleaning agents, as they could damage the plastic exterior of the SPM-1.

Caution Do not autoclave or immerse the SPM-1 as damage may occur. If the SPM-1 is exposed to liquids, turn off the unit, remove the power cord and thoroughly dry the unit before reapplying power.

Warning To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified personnel.

Caution Read Directions for Use before connecting to bedside patient monitors.

Caution Grounding reliability can only be achieved when connected to Hospital Grade Receptacle.

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Caution Where the integrity of the external PROTECTIVE EARTH CONDUCTOR arrangement is in doubt, the equipment shall be operated from its internal electrical power source (battery).

Caution This equipment should not be used with high frequency surgical equipment.

Warning Integra NeuroSciences catheters are for single use only. Do not attempt to re-sterilise or reuse. Integra NeuroSciences cannot assume any responsibility for damage caused by re-sterilised catheters. Used catheters should be considered as a potential biohazard. Follow all established laws and regulations pertaining to the handling and disposal of biohazardous materials.

Caution The SPM-1 does not measure temperature parameters, and is not appropriate for use with temperature catheters.

Caution The SPM-1 measurement range is –10 mmHg to +125 mmHg.

Caution The SPM-1 contains Static Sensitive Components. Observe proper ESD precautions.

Caution The SPM-1 complies with the electromagnetic compatibility requirements of IEC 60601-1-2 (second edition) and EN 60601-1-2: 2002. However, there is no guarantee that electromagnetic interference will not occur in a given situation. If this device causes harmful interference or is subjected to harmful interference, the user may be able to correct the situation using the following measures:

- Increase the separation between adjacent and stacked devices
- Re-orient the device cabling
- Connect the device to an outlet or a circuit different from other devices
- Consult the manufacturer or distributor for further assistance
- Refer to the SPM-1 accompanying documents for additional electromagnetic information

Caution The use of accessories, transducers, or cables other than those intended for use with the SPM-1 and provided by Integra NeuroSciences may result in increased emissions or decreased immunity of the overall system.

Caution Accessory equipment connected to the SPM-1 must be certified to the respective IEC standard (i.e. EN 60601-1 for medical equipment). All configurations shall comply with the system standard EN 60601-1-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard EN 60601-1-1.

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1.5 Shipping Instructions

A shipping container is available. To insure proper preparation and shipping, contact Integra NeuroSciences for instructions.

1.6 Applicability

This Technical Manual is applicable to the Single-Parameter Monitor with LED display, Model SPM-1. Contact Integra NeuroSciences for information on equipment not covered in this manual.

Integra NeuroSciences reserves the right to change specifications and procedures without notice.

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1.7 Product Description

The Integra NeuroSciences Single-Parameter Monitor (SPM-1) is a compact, portable device for use with sterile, single-use Camino® 110-4 Series Intracranial Pressure catheters (excluding BT & HMT). Intracranial pressure is measured at the catheter tip, eliminating the need for external transducers, fluid, pressure tubing, and flush devices. The SPM-1 does not measure temperature and is not recommended for use with temperature catheters. The following catheters are appropriate for use with the SPM-1:

110-4B: OLM Parenchymal Pressure Monitoring Kit
110-4G: Post Craniotomy Subdural Pressure Monitoring Kit
110-4H: Ventricular Bolt Pressure Monitoring Kit
110-4HM: Micro Ventricular Bolt Pressure Monitoring Kit
110-4L: Camino® Intracranial Pressure Monitoring Kit with Licox® Bolt Fitting

When connected to a PAC-2 Preamp Cable and a 110-4 series catheter the SPM-1 provides a continuous numeric display of mean ICP values in the range of -10 mmHg to +125 mmHg. Mean ICP values outside of this measurement range result in the out-of-range indicator "---" regardless of the measurement range of the catheter.

When plugged into AC power the SPM-1 rechargeable battery automatically charges. The SPM-1 will typically operate for 4 hours (2 hours minimum) on battery power. The system is very portable due to an integrated handle/bed rail mount and pole clamp. The extended battery time, portability, light weight, and small profile make the SPM-1 ideal for monitoring ICP during patient transport.

The SPM-1 provides a user adjustable high ICP alarm. Visual and audible alarms are initiated when the mean ICP exceeds the user adjustable alarm limit setting. The audible alarm may be disabled for three minutes by a single button press. The visual alarms cannot be disabled.

To display the ICP waveform the SPM-1 must be connected to an external patient monitor. Although the SPM-1 is intended to be a stand-alone ICP monitor, the high frequency response of its fibreoptic based catheter provides excellent waveform fidelity at the patient monitor output, allowing detailed waveform analysis. The SPM-1 also provides a simple means for zeroing the patient monitor and verifying its calibration.

The SPM-1 may be connected to a patient monitor by using the accessory PMIO-SPM cable. In some instances an accessory adapter cable ICP-XX is also required. Contact Integra NeuroSciences Customer Service for specific requirements.

SPM-1 trend data is available at the RS-232 output port. When an IBM compatible computer is connected to the RS-232 port, accessory software MPM-1-SDC may be used to collect the trend data and display it numerically or graphically. This data may be printed out when the computer is connected to a printer.

If desired, the SPM-1 may be used in conjunction with the Integra NeuroSciences' Licox Brain Tissue Oxygen Monitoring System. This provides a cost-effective means for monitoring ICP, brain tissue oxygen, and temperature from a single burr hole. When used in this manner the Camino 110-4L catheter is required since it is specially designed for use with Licox multi-lumen IMC introducers. Refer to the Directions for Use which accompany each of these products.

Note: Temperature and oxygen levels will be displayed on the Licox Monitoring System.

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1.8 Description of Controls and Indicators

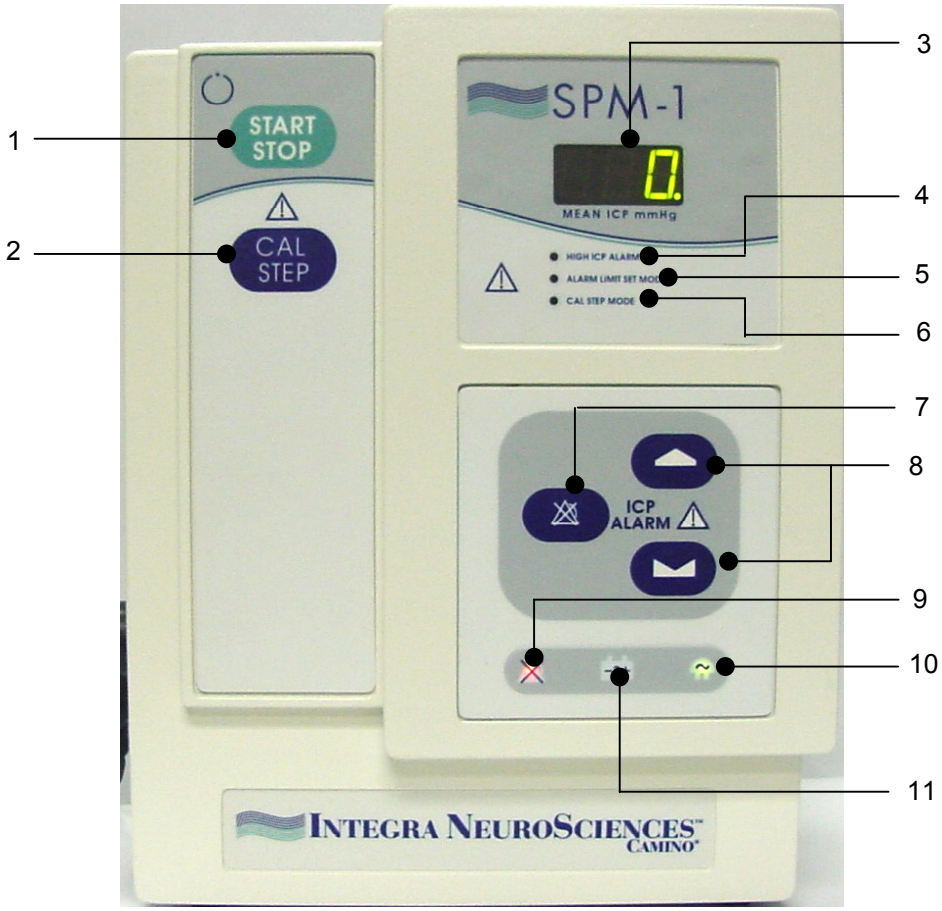

Figure 1-1
SPM-1 Front Panel

1. **START/STOP BUTTON** – Press to turn the SPM-1 on or off.

2. **CAL STEP BUTTON –** Press to initiate the CAL STEP MODE. Use to calibrate or check correlation of an external patient monitor. Press and hold to momentarily interrupt normal pressure display and substitute an artificially generated pressure signal, which will appear on both the SPM-1 display and the external patient monitor. Each press advances to the next pressure value in the following series: 0, 20, 40, 100, 125, and back to 0.

3. **LED DISPLAY –** Normally displays:
    - Mean intracranial pressure (ICP) in mmHg.
    - Momentarily displays the ICP alarm limit setting when an UP or DOWN button press initiates the ALARM LIMIT SET MODE.
    - Momentarily displays an artificially generated pressure value when a CAL STEP BUTTON press initiates the CAL STEP MODE.

4. **HIGH ICP ALARM INDICATOR –** This red LED illuminates when the mean ICP is greater than the ICP alarm limit setting.

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5. **ALARM LIMIT SET MODE INDICATOR –** This green LED illuminates to indicate the SPM-1 is in the ALARM LIMIT SET MODE. In this mode the displayed value is the ICP alarm limit setting. This occurs whenever the UP or DOWN buttons are pressed.

6. **CAL STEP MODE INDICATOR –** This green LED illuminates to indicate the SPM-1 is in the CAL STEP MODE. In this mode the displayed value is an artificially generated pressure signal. This occurs whenever the CAL STEP button is pressed.

7. **SILENCE ALARM BUTTON –** Press to silence the audible alarm for 3 minutes. When the audible alarm is silenced the ALARM DISABLED INDICATOR will blink on and off.

8. **UP AND DOWN BUTTONS –** Press the UP and DOWN buttons to initiate the ALARM LIMIT SET MODE. In this mode the ICP alarm limit may be set to values between 1 to 75 mmHg, or off. Press the UP or DOWN button once to view the current alarm limit setting. Press repeatedly or continuously to adjust the alarm limit setting. When set to off the ALARM DISABLED INDICATOR will remain illuminated.

9. **ALARM DISABLED INDICATOR –** Remains continually illuminated when the ICP alarm limit is set to off. Blinks on and off when the audible alarm is temporarily silenced due to a SILENCE ALARM BUTTON press.

10. **AC POWER INDICATOR -** Illuminates when the SPM-1 is connected to AC power. The battery will charge whenever this indicator is illuminated.

11. **LOW BATTERY INDICATOR –** Illuminates when the SPM-1 is operating on battery power and approximately fifteen minutes of battery life remains.

Note: Connect the SPM-1 to AC power as soon as possible to maintain battery charge.

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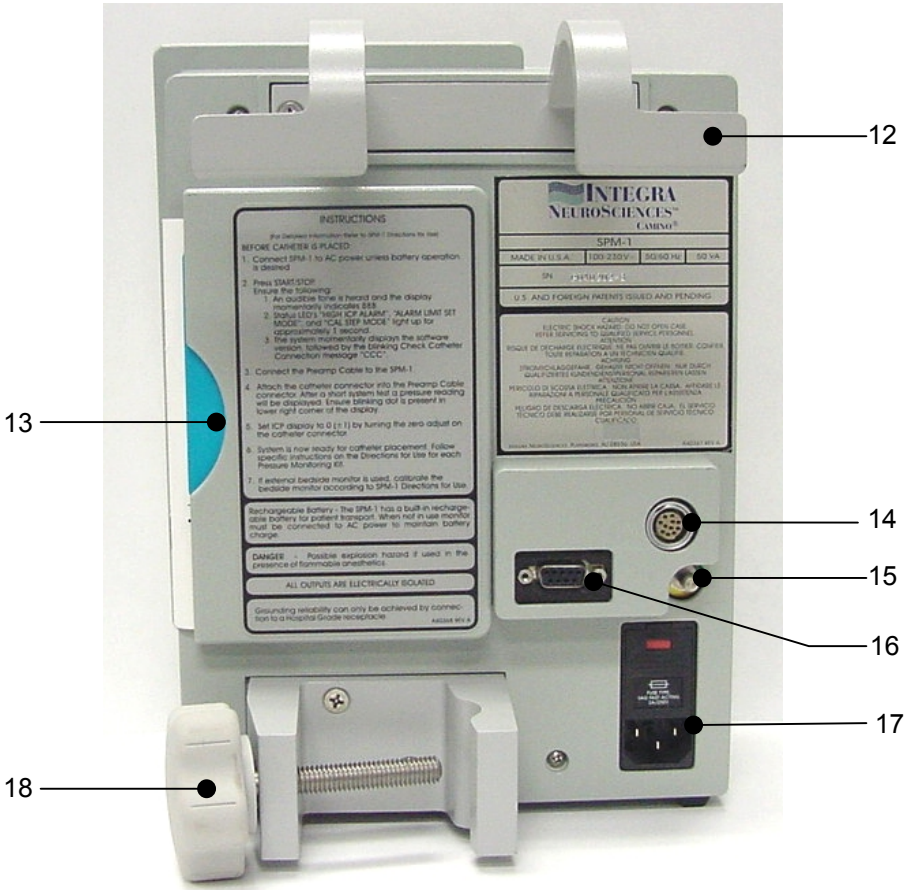

Figure 1-2
SPM-1 Rear Panel

12. **COMBINATION CORD WRAP, HANDLE** and **BED RAIL MOUNT**

13. **DFU POCKET** – Storage location for the Directions for Use booklet.

14. **PATIENT MONITOR CONNECTOR** – Used to transfer ICP data to an external patient monitor.

15. **EQUIPOTENTIAL CONNECTOR** – Used as the connection point for equipotential systems.

16. **RS232 CONNECTOR** – Used to transfer ICP data to the MPM-1-SDC data acquisition program. Please contact Integra NeuroSciences for details on use of this accessory.

17. **AC CONNECTOR** – Attachment point for the AC power cord. Requires 100 to 230 VAC at 50 or 60 Hz. The unit must be plugged into an AC source in order to maintain a charge on the internal battery.

18. **POLE CLAMP –** Used to secure the SPM-1 to an equipment pole.

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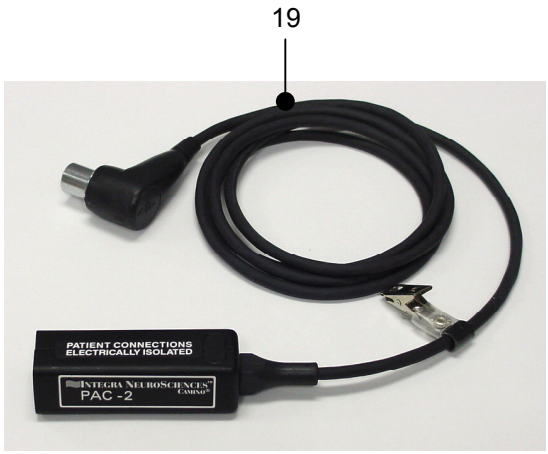

Figure 1-3
PAC-2 Preamp Cable

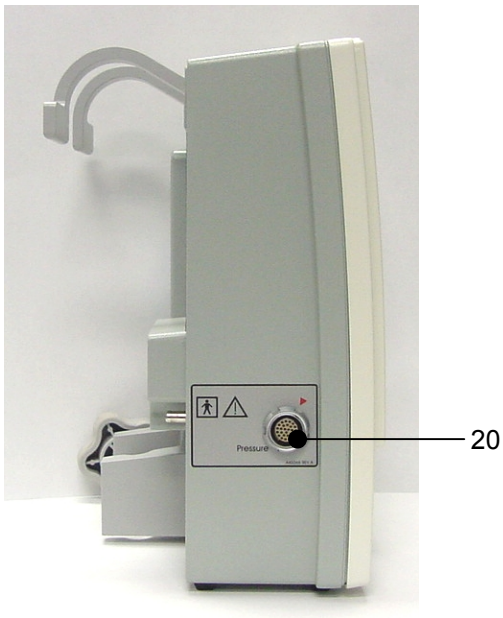

Figure 1-4
ICP Input Connector

19. **PAC-2 PREAMP CABLE** – Provides an interface between the SPM-1 and compatible Camino® ICP catheters. The PAC-2 Preamp Cable is shipped non-sterile and may be sterilised with ethylene oxide.

20. **ICP INPUT** – Connection point for the PAC-2 Preamp Cable.

Note: The preamp cable is shipped non-sterile. The current recommended method of sterilisation is ethylene oxide. It is the users responsibility to identify and validate the appropriate sterilisation cycle. For recommended guidelines, please refer to ANSI/AAMI/ISO 11135 EtO Process Guidelines (ANSI/AAMI/ISO Recommended Practice Guideline for Industrial Ethylene Oxide Sterilisation of Medical Devices et al). For additional guidance on sterilisation, please contact Integra Neurosciences Technical service.

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1.9 System Accessories

PMIO-SPM CABLE

Provides an interface for data transfer between the SPM-1 and a patient monitor.

Figure 1-5
PMIO-SPM Cable

ICP-XX ADAPTER CABLE

Provides an interface for connecting the PMIO-SPM Cable to patient monitors. Replace the "XX" with the appropriate part number that provides compatibility to specific patient monitors.

Call Integra NeuroSciences customer service for adapter cable compatibility requirements.

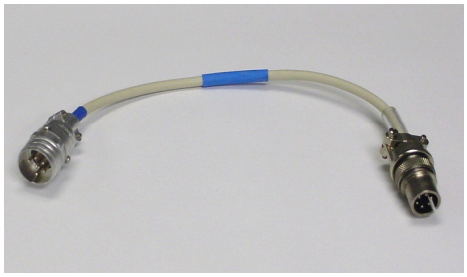

Figure 1-6
ICP-XX Cable

ICP CATHETER

A variety of Pressure Monitoring Kits provide the fibreoptic-based Camino® catheter for parenchymal, intraventricular, or subdural monitoring.

Directions for Use are provided with each Pressure Monitoring Kit.

Camino® Pressure Monitoring Kits appropriate for use with the SPM-1 include:

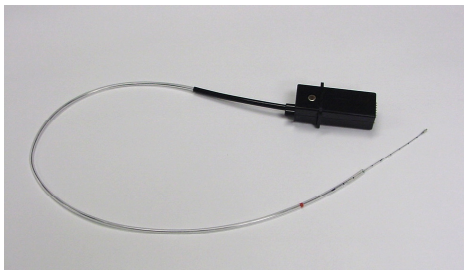

Figure 1-7
ICP Catheter

Model	Description
110-4B	OLM Parenchymal Pressure Monitoring Kit
110-4G	Post Craniotomy Subdural Pressure Monitoring Kit
110-4H	Ventricular Bolt Pressure Monitoring Kit
110-4HM	Micro Ventricular Bolt Pressure Monitoring Kit
110-4L	Camino® Intracranial Pressure Monitoring Kit for use with the Licox® IMC Introducer

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MPM-1-SDC

The MPM-1-SDC data acquisition software is intended to be used as a tool to gather, summarise and trend data generated by the SPM-1. It does not offer or suggest any diagnosis or course of action. When the SPM-1 RS-232 CONNECTOR is connected to an IBM compatible computer or laptop the MPM-1-SDC software provides:

- Display graphs of monitoring trends for user-selected time intervals between 1 to 24 hours (Figure 1-8)
- Display numeric monitoring trends up to the last 24 hours of monitoring
- Printing of graphed trend data and numerical trend data when the computer is connected to a printer
- Log trend data to disk for trend analysis
- For detailed information refer to instructions included with the MPM-1-SDC software.

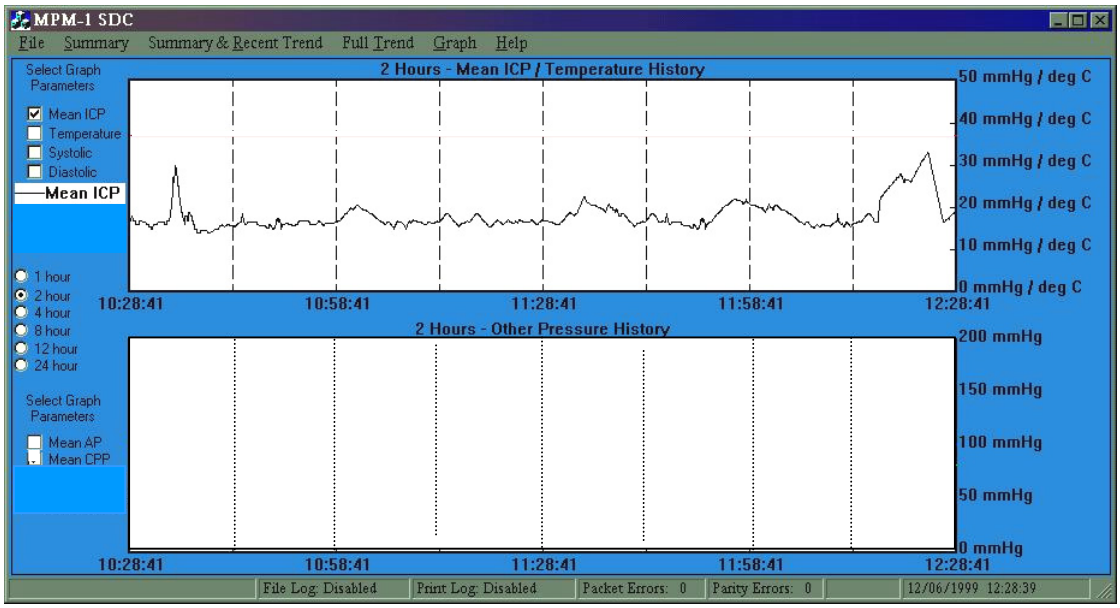

Figure 1-8
MPM-1-SDC Graph

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1.10 Technical Specifications

Intracranial Pressure (ICP)

Sensor Type:	Camino® fibreoptic pressure transducer
Measurement Range:	-10 to +125 mmHg
Linearity and Hysteresis:	See individual catheter specifications
Reference Pressure:	Atmospheric

Display

Type:	3 Digit, 7 Segment LED Numerical Display
Display Resolution:	1 mmHg
Display Digit Height:	0.56”
Parameters Displayed:	Mean ICP

Power Requirements

100-230 V, 50/60 Hz, 50 VA

Mean ICP Alarms

Alarm Range:	User adjustable from 1 to 75 mmHg (1 mmHg steps), or off
Audible Alarm Frequency:	ON 0.5 seconds and OFF 0.5 seconds
Audible Alarm Silence:	Single button press, active for 3 minutes ±10%
Visual Alarm:	Continuously illuminated red LED while in an alarm condition Blinking Mean ICP display when system is in an alarm condition

Monitor Inputs

PAC-2 Preamp Cable for use with Camino® 110-4 series non-temperature ICP catheters

Patient Monitor Outputs

Isolation:	Electrically isolated SIP/SOP per IEC 60601-1
Output Sensitivity:	5μV/V/mmHg
Connector Type:	6-Pin CANNON WK-6
Resolution:	0.125 mmHg resolution
Calibration Output Signals:	0, 20, 40, 100, 125 mmHg
Frequency Response:	1000 Hz (-3dB)

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RS-232 Serial Data Outputs

Isolation:	Electrically isolated SIP/SOP per IEC 60601-1
Software Compatibility:	MPM-1-SDC Data Acquisition Software
Available Data:	Mean ICP, Raw ICP, Systolic ICP, Diastolic ICP, Trend ICP, Alarm Status
Connector Type:	DB-9
Data Rate:	19.2 kBPS

Battery

Type:	Rechargeable, sealed lead acid
Recharge Time:	8-10 hours to full charge
Operation Time:	2-4 hours from full charge

Monitor Operation Limits

Temperature:	15°C to 40°C (59°F to 104°F)
Pressure:	700 hPa to 1060 hPa (20.67 inHg to 31.30 inHg)
Humidity:	20% to 95% RH

Shipping/Storage Limits

Temperature:	-20°C to 50°C (4°F to 122°F)
Pressure:	500 hPa to 1060 hPa (14.76 inHg to 31.30 inHg)
Humidity:	20% RH to 95% RH non-condensing

Physical Dimensions

Size:	282 mm H x 216 mm W x 163 mm D (11.1” x 8.5” x 6.4”)
Weight:	4.1 kg (9.2 lbs.)

IEC-60601-1 Class of Equipment: Class 1

Protection Against Fluids: Ordinary

Mode of Operation: Continuous

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1.11 Limited Warranty

INTEGRA NEUROSCIENCES warrants that each new INTEGRA NEUROSCIENCES product is free from defects in material and workmanship under normal use and service for a period of two (2) years (except as otherwise expressly provided as to accessory items) from the date of delivery by INTEGRA NEUROSCIENCES to the first purchase, but not beyond the “Expiration” date stated on any product labeling. Surgical instruments are guaranteed to be free from defects in material and workmanship when used normally for their intended purpose and in accordance with instructions. Any covered product that is placed by INTEGRA NEUROSCIENCES under a lease, rental or installment purchase agreement and that requires repair service during the term of such placement agreement shall be repaired in accordance with the terms of such agreement. If any such defect occurs during the warranty period or term of such placement agreement, the purchaser should communicate directly with the INTEGRA NEUROSCIENCES home office. If returned to INTEGRA NEUROSCIENCES at its home office, repair or replacement will be carried out at INTEGRA NEUROSCIENCES' sole discretion, at INTEGRA NEUROSCIENCES' expense, subject to the terms of this warranty and applicable agreements. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to INTEGRA NEUROSCIENCES shall be at CUSTOMER’s risk.

IN NO EVENT SHALL INTEGRA NEUROSCIENCES BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA NEUROSCIENCES PRODUCT. Further, this warranty shall not apply to, and INTEGRA NEUROSCIENCES shall not be responsible for, any loss arising in connection with the purchase or use of any INTEGRA NEUROSCIENCES product that has been repaired by anyone other than an authorised INTEGRA NEUROSCIENCES service representative or altered in any way so as, in INTEGRA NEUROSCIENCES' judgment, to affect its stability or reliability, or that has been subject to misuse, negligence or accident, or that has been used otherwise than in accordance with the instructions furnished by INTEGRA NEUROSCIENCES. THIS LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON INTEGRA NEUROSCIENCES' PART AND INTEGRA NEUROSCIENCES NEITHER ASSUMES NOR AUTHORISES ANY REPRESENTATIVE OR OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH INTEGRA NEUROSCIENCES’ PRODUCTS.

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1.12 Contact Information

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For Technical Support:
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5955 Pacific Center Boulevard
San Diego, CA 92121-4309

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x 215 for Technical
Support
Technical Support Fax: (858) 455-5874
Technical Support e-mail: camts@integra-ls.com

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2.1 Setting Up the SPM-1

SPM-1 Placement

Prior to each use carefully inspect the SPM-1 power cord and cables to assure each item is undamaged. The SPM-1 may be placed on an appropriate table, or, if desired, the unit may be hung on a bed rail, or mounted on an equipment pole and secured using the POLE CLAMP.

Note: The SPM-1 POLE CLAMP can accommodate equipment poles up to 1.2" diameter. To ensure patient safety, do not place the SPM-1 in any position that might cause it to fall on the patient. Make sure the SPM-1 is properly attached to equipment pole and tightened. The SPM-1 BED RAIL HOOK will accommodate a bed rail up to 2" diameter.

AC Power Operation

If AC power operation is desired, plug the hospital grade power cord provided by Integra NeuroSciences into the AC CONNECTOR on the SPM-1. Plug the male connector of the power cord into a properly grounded AC outlet. The SPM-1 will operate on AC power from 100-230 VAC, 50 or 60 Hz. Verify the AC POWER INDICATOR is illuminated when AC power is connected to the unit. Connect the SPM-1 equipotential connector to the equipotential system, if required.

Battery Operation

The SPM-1 has an internal battery that can be used to power the unit during patient transport or when AC power is not available. A new, fully charged battery will typically provide up to 4 hours (2 hours minimum) of operation. The LOW BATTERY INDICATOR will illuminate when approximately fifteen minutes of operational time is available on the existing battery charge. If this occurs plug the unit into AC power to continue monitoring. The SPM-1 battery recharges whenever it is plugged into AC power. When not being used, it is recommended that the unit remain connected to AC power in order to maintain the battery charge.

Connecting a Patient Monitor

If desired, connect the SPM-1 to an external patient monitor using the PMIO-SPM Cable and the appropriate Adapter Cable. Ensure these accessory cables are available prior to patient usage. Call Integra NeuroSciences Customer Service or your Neurospecialist for additional information.

Connecting to an IBM Compatible Computer

If desired, the SPM-1 RS-232 port may be connected to an IBM compatible computer through a 9-pin straight through serial cable (not provided by Integra NeuroSciences). The MPM-1-SDC software provides a means for viewing and printing graphs and numerical data associated with monitoring trends.

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Using the SPM-1 in Conjunction with the Licox® System

If desired, the SPM-1 may be used in conjunction with the Integra NeuroSciences' Licox® Brain Tissue Oxygen Monitoring System. This provides a cost-effective means for monitoring ICP, brain tissue oxygen, and temperature from a single burr hole. When used in this manner the Camino® 110-4L catheter is required since it is specially designed for use with Licox® multi-lumen IMC introducers. Refer to the Directions for Use which accompany each of these products.

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2.2 Using the SPM-1

Turning on the SPM-1

Turn on the SPM-1 by pressing the START/STOP button on the front panel. An audible tone will sound and the LED DISPLAY will momentarily indicate 888. The red HIGH ICP ALARM INDICATOR, green ALARM LIMIT SET MODE INDICATOR, and green CAL STEP MODE INDICATOR will also be momentarily illuminated permitting verification of these indicators. The SPM-1 software version is displayed, followed by the blinking Check Catheter Connection message "CCC" (Figure 2-1). If the unit is operating from AC power verify the AC POWER INDICATOR is illuminated.

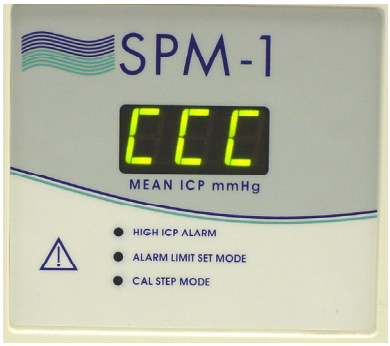

Figure 2-1
"CCC" Message

Connecting the PAC-2 Preamp

Connect the PAC-2 Preamp Cable to the SPM-1 ICP Input (Figure 2-2). Note the red alignment mark on the cable connector and the side panel.

Figure 2-2
Preamp Cable to SPM-1 ICP Input

Connecting the Catheter

Select the desired Camino Pressure Monitoring Kit. Specific Directions for Use are provided with each Pressure Monitoring Kit. Remove the catheter from the kit tray and firmly connect the catheter connector into the preamp connector (Figure 2-3).

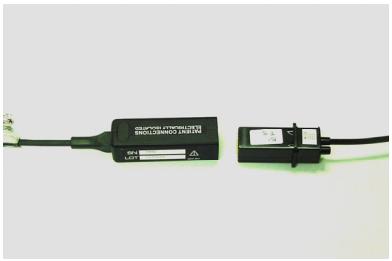

Figure 2-3
Catheter Connector to Preamp Connector

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Data Update Verification

After a short system test, indicated by moving dashes "-" across the display, the SPM-1 will display a pressure reading*.

A blinking dot in the lower right corner of the display lights up each time the display is updated with a new measurement. This permits verification of continual data updates (Figure 2-4).

* If the system displays the out-of-range error message consisting of three dashes “---“ refer to section 6.4, “Error Messages”.

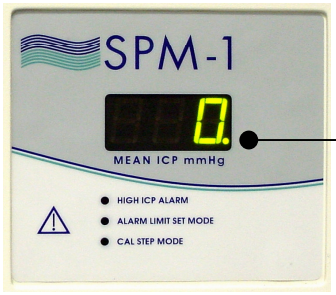

Figure 2-4
Initial ICP Display

Zeroing the Catheter

Before inserting the catheter into the patient, ensure that the SPM-1 display indicates an ICP Pressure of “0 mmHg” (Figure 2-4). If not, use the zero adjust tool from the Catheter Kit to turn the zero adjustment (Figure 2-5) on the bottom side of the transducer connector until the displayed ICP is “0 mmHg”. Refer to the catheter Directions for Use for proper insertion technique.

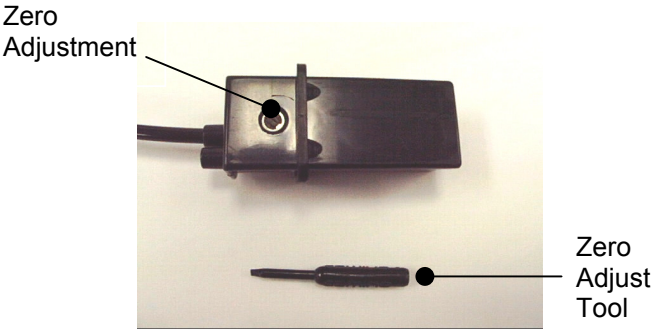

Figure 2-5
ICP Catheter Transducer

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Zeroing a Patient Monitor

If the SPM-1 is connected to an external patient monitor, the CAL STEP button (Figure 2-6) may be used to calibrate or balance the patient monitor. Pressing the CAL STEP BUTTON causes the SPM-1 to enter the CAL STEP MODE. The CAL STEP MODE temporarily interrupts normal pressure display and substitutes a calibration pressure signal on both the SPM-1 and on the external patient monitor. The CAL STEP MODE INDICATOR is illuminated while in this mode. Each press of the CAL STEP BUTTON advances the calibration pressure signal to the next value in the following series: 0, 20, 40, 100, 125 and back to 0. Press the CAL STEP BUTTON repeatedly until 0 mmHg is displayed on the SPM-1. While keeping the button depressed to maintain 0, simultaneously zero the patient monitor, wait until the patient monitor responds, then release the CAL STEP BUTTON. Within a few seconds the SPM-1 will exit the CAL STEP MODE and return to normal pressure display. Note that the CAL STEP BUTTON may be used any time, and does not affect the transducer calibration.

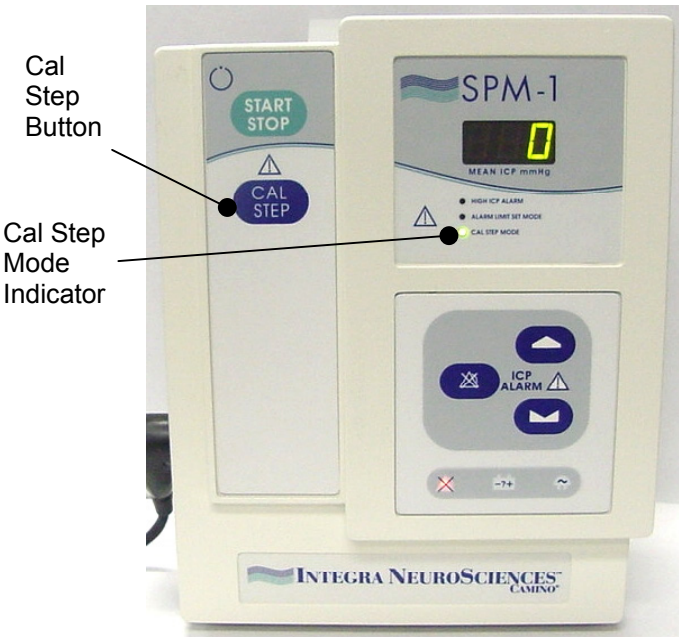

Figure 2-6
Cal Step Button

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Setting the ICP Alarm

The ICP alarm limit may be set from 1 to 75 mmHg or off. If the mean ICP exceeds the ICP alarm limit the SPM-1 will initiate audible and visual alarms as described below. Pressing the UP or DOWN buttons causes the SPM-1 to enter the ALARM LIMIT SET MODE. The ALARM LIMIT SET MODE momentarily interrupts the normal pressure display and substitutes the current ICP alarm limit setting on the display. The ALARM LIMIT SET MODE INDICATOR is continually illuminated while in this mode (Figure 2-7). To adjust the ICP alarm limit press and hold the UP or DOWN buttons. To view the current ICP alarm limit press the UP or DOWN button once. Within a few seconds the SPM-1 will exit the ALARM LIMIT SET MODE and return to normal pressure display. The ICP alarm limit may be turned off by continually pressing the DOWN button (Figure 2-8). The ALARM DISABLED INDICATOR is continually illuminated when the ICP alarm limit is turned off (Figure 2-9).

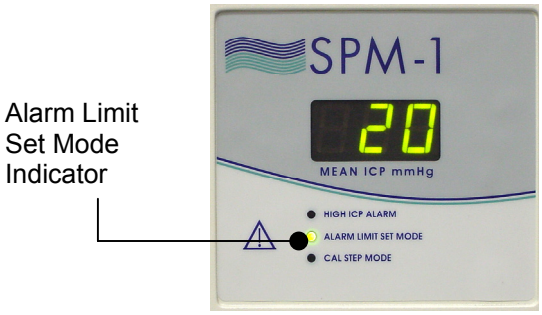

Figure 2-7
Alarm Limit Set Mode

Figure 2-8
ICP Alarm Limit Turned Off

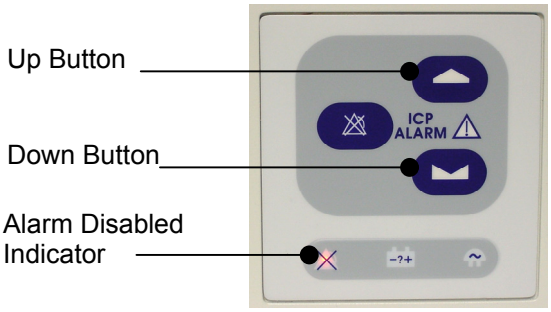

Figure 2-9
Up, Down Buttons and
Alarm Disabled Indicator

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Alarm Indicators

If the mean ICP exceeds the alarm limit setting the following alarms are initiated:

- An audible alarm is cycled on and off twice per second.
- The red HIGH ICP ALARM INDICATOR is continually illuminated.
- The displayed mean ICP value blinks.

Silencing the Audible Alarm

The audible alarm may be silenced for three minutes by pressing the SILENCE ALARM BUTTON. The ALARM DISABLED INDICATOR will blink while the audible alarm is disabled (Figure 2-10). After three minutes have elapsed the audible alarm will automatically become re-activated and sound an alarm if the mean ICP exceeds the ICP alarm limit setting.

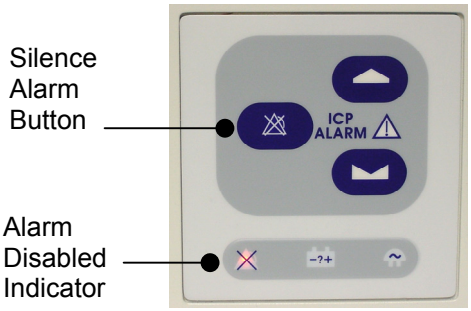

Figure 2-10
Silence Alarm Button &
Alarm Disabled Indicator

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3.1 The Camino® Catheter

The Camino® 110-4 Series of catheters (Figure 3-1) is based on an intensity-modulating fibreoptic scheme using a bellows as the primary transducer. Light from a LED source is transmitted down one fibre, called the sender. The light is reflected off the polished surface of the bellows and is collected by another fibre, called the receiver. Changes in bellows position due to pressure shifts modulate the intensity of the reflected light. The light is sensed by a light sensitive device, amplified, filtered, and digitised.

A second pair of fibres has the same characteristics and length. They are mounted similarly within the catheter and exposed to the same light source. These fibres are connected by a reference junction. The purpose of this scheme is to allow a means for monitoring LED light source variations that are unrelated to pressure changes in the bellows. Light intensity changes in this fibreoptic loop may be attributed to non-pressure events such as bending of the fibre or semiconductor temperature coefficients. The SPM-1 automatically compensates for these changes by adjusting the intensity of the LED source. The result is a stable, unchanging light intensity delivered to the surface of the bellows.

The transducer has a close to linear response throughout the –10 to 125 mmHg measurement range of the SPM-1. However, the catheter response must be linearised in order to optimise measurement accuracy. This is accomplished by applying known pressure values to the catheter during manufacture and recording known data points along the catheter's pressure response curve. These data are then encoded into the catheter. When the catheter is connected to an SPM-1 the encoded data is read and used to construct a software lookup table which is used to linearise the catheter response in real-time.

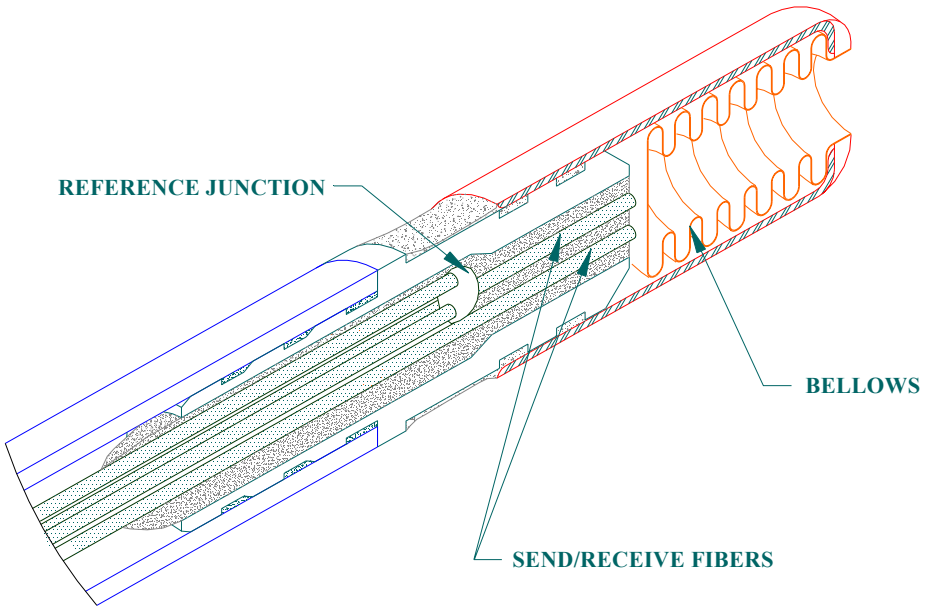

Figure 3-1
Camino Catheter

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3.2 SPM-1 Digital Board

The SPM-1 Digital Board consists of microprocessor-controlled circuitry, a Programmable System Device (PSD) and associated circuits. The Programmable System Device provides 64K EPROM and 2K SRAM, memory and I/O space decoding, as well as certain logic functions. Also there is an external 32K SRAM for other temporary scratchpad and memory functions. Major functions handled by the Digital Board are described below:

Pressure Processor and Related Functions

- Establishes communication with the catheter.
- Interprets encoded information within the catheter.
- Sends digitised, serial data to configure the system digital-to-analogue converters (Span, Zero, Ref) based upon encoded catheter information for zero, span, and reference.
- Provides system control signals to the analogue-to-digital converter and multiplexors.
- Ensures the Reference Loop is maintained (catheter is not disconnected, nor inoperational).
- Receives intracranial pressure and membrane switch status data via its serial link from Board 2.
- Sends digitised serial data and control signals to the patient monitor output circuitry.
- Performs software linearisation of received ICP data based on encoded catheter information for curves 1, 2.
- Transfers the linearised ICP data, with handshake, to the video processor.

Video Processor and Related Functions

- Receives linearised ICP data from the pressure processor. Performs time-weighted averaging of the data, and sends the digital serial data to the LED Board for the LED display. Controls all LED's on the LED board.
- Monitors most of the membrane switch inputs and takes appropriate action.
- Sends digital serial data to the isolated RS-232 circuitry for external data acquisition.
- Controls the state of the Alarm Disabled LED on the front panel.
- Controls the state of the system audible alarm.

Miscellaneous Functions

- Watchdog circuitry monitors system software to ensure proper software operation.
- System audible alarm circuitry. Is activated by the system watchdogs or the video processor.

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- System clocks provide processors and control circuits with timing signals.
- A current-mode, flyback topology switching regulator with isolation transformer provides isolated power for the patient monitor output circuitry.
- Isolated RS-232 circuitry provides digital data for external data acquisition.
- Voltage regulators provide regulated +7Volts, -6Volts for the Analogue Board.

3.3 SPM-1 Analogue Board

LED Drive

The LED (located in the catheter) is pulsed by the LED Drive at an approximately 1.3 kHz rate, with an ON time that is 1/16 of the OFF time, i.e., it is ON for about 83 microseconds and OFF for 1.25 milliseconds. This allows for a chopper amplifier style sampling of signals at a higher frequency followed by low-pass filtering and the implementation of a unique method of subtracting dark currents and unwanted signals. The end result is a drift-free system that produces an output with a large signal-to-noise ratio.

ICP Signal Processing

The Analogue Board utilises digital-to-analogue converters (DAC) configured as digitally controlled attenuators in order to normalise the response of each catheter. The zero DAC and span DAC are configured based upon information encoded within the catheter. Each DAC provides 12 bits of accuracy, allowing 4096 different levels of attenuation to be selected. When the SPM-1 detects the presence of a new catheter the information encoded in the catheter is read by the SPM-1 and the DACs are configured accordingly. The DACs adjust the response curve (pressure/voltage) of each catheter such that all catheters have an identical response curve at the input of the system's analogue-to-digital converter. After the signal is digitised it is sent as a serial data stream to the Digital Board's pressure processor where it is linearised. The linearisation process is performed differently on each catheter, depending upon the information gained during the manufacture of the catheter and encoded within the catheter. The result is a high fidelity, instantaneous ICP signal that is delivered to the external patient monitor. The instantaneous ICP data is also transferred to the video processor where it is converted into mean ICP by a time-weighted averaging software algorithm. Mean ICP data is sent in a serial data stream to the LED Board for presentation on the system's LED display. The Video Processor also determines systolic, diastolic, and trend ICP data in real-time. The instantaneous ICP, mean ICP, systolic, diastolic, and trend ICP data are sent to the isolated RS-232 port and may be viewed using the accessory MPM-1-SDC data acquisition software.

Reference Signal Processing

A second pair of fibres with the same characteristics and length as the fibres used to process the ICP data is present in the catheter. They are mounted similarly within the catheter and exposed to the same light source. These fibres are connected together by a reference junction. The electronic circuitry used to condition this signal is essentially identical to that used to condition the ICP data, and therefore tracks variations in the ICP circuit that may change due to component temperature coefficients or other error producing variables. The purpose of this scheme is to allow a means for automatically

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correcting changes that may occur which are not pressure related. The SPM-1 automatically compensates for these changes by adjusting the intensity of the LED source that drives the ICP and reference circuits. The result is a stable, unchanging light intensity delivered to the surface of the bellows and automatic compensation of error producing variables within the SPM-1.

Zero Adjustment Signal Processing

The zero adjustment located on all 110-4 Series catheters provides a means for the user to adjust the system to 0 mmHg prior to use. The SPM-1 delivers a stiff current source to the zero adjustment potentiometer and measures the resulting voltage. Based upon information encoded into each catheter and the setting of the zero pot the SPM-1 adjusts the zero DAC on the Analogue Board. This is a normal system adjustment that allows elimination of any offsets before the system is used. This adjustment must be performed before inserting the catheter into the patient.

Patient Monitor Signal Processing

The Patient Monitor Input/Output (PMIO) provides an interface to most patient monitors. The output sensitivity is 5µV/Vexc/mmHg. As described in the ICP Signal Processing section, serial data representing linearised instantaneous ICP is sent from the pressure processor to the PMIO circuit. The serial stream is transferred across an isolation boundary consisting of optoisolators and converted into an analogue signal by a digital-to-analogue converter. The signal is then scaled and converted into a differential signal. This high precision circuitry emulates the direct connection of a standalone wheatstone bridge transducer.

The output can be described as follows:

$$V_{out} := 5 \cdot 10^{-6} \cdot V_{exc} \cdot \left(512 \cdot \frac{counts}{4096} - 150 \right)$$

Where:

V_{exc} is the differential voltage supplied by the patient monitor

counts is the digital value supplied by the SPM-1 to the DAC

This equation implements the medical specification for transducers used with bedside monitors--5µV/Vexc/mmHg, that is, 5µV output per 1 volt of excitation for 1 mmHg, except that it additionally describes the pressure/ADC count scale used by the SPM-1. The SPM-1 provides 1200 counts to represent 0 mmHg, and uses 8 counts for each mmHg. Therefore, to represent 100 mmHg the SPM-1 uses:

1200 counts + (8 counts/mmHg * 100 mmHg) = 2000 counts

As an example, assume V_{exc} = 5V and *counts* = 2000 (representing a reading of 100mmHg). V_{out} then equals 2.5 mV.

Note: that at 1200 counts (0 mmHg), the output remains at zero regardless of excitation voltage. Therefore this circuit satisfies the requirement of proportionate gain without undue influence from the normal offset. Also note that each integer value of pressure is represented by 8 counts in the above equation. Therefore each integer value of pressure is resolved into 8 discrete values, providing a resolution of 0.125 mmHg at the patient

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monitor output. However, most patient monitors display and record ICP data in whole integers.

3.4 SPM-1 AC Input Board

The AC Input Board of the Power Supply provides off-line conversion from the AC mains to +16.5 volts of isolated, regulated power for Board 4.

Input requirements:

- 90 VAC (low-line Japan) to 264 VAC (high-line Europe).

Output drives 3 separate loads:

- The monitor circuitry (when the monitor is ON).
- A dummy load which minimally loads this supply (when the monitor is OFF).
- The battery charging circuit.

Features:

- Power is taken directly from the AC mains.
- Fixed frequency, current mode pulse width modulator topology.
- Isolation from the LINE exceeds 4500 VAC for safety.
- Output noise is in sync with the master clock to minimise beat frequency noise.
- Output level is controlled by an isolated optocoupler with bandgap reference.

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3.5 SPM-1 DC Output Board

The DC Output Board of the Power Supply provides DC-DC conversion from the source to +5V for Logic, +15V for LED Drive, +9V and -8V for OpAmps. This power is extracted from either of two sources, the 16.5 volts from Board 3 or the nominal 12 volts from the lead acid battery.

Input requirements:

- 16.5 volts from Board 3 (if AC power is available and connected).
- 12 volts, nominal, from the battery (10.8 volts, minimum).

Outputs:

- +5 volts for Logic.
- +15 volts for LED drive.
- +9 volts for Operational Amplifiers.
- -8 volts for Operational Amplifiers.

Features:

- AC LED is illuminated when AC power is connected.
- BATTERY LOW lamp is illuminated (whenever the unit is ON and using battery power) and the battery is discharged to less than 11.3 volts, warning that the battery charge is depleted.
- Long shelf life for fully charged battery (less than 10 uA leakage current).
- 5 volt output controlled by bandgap reference; other outputs track this output given nominal loading.
- Output noise is in sync with master clock to minimise beat frequency noise.
- Shutdown of Board 4 supply automatically occurs when the battery is discharged to less than 10.8 volts.
- Battery charging is current limited to about 330mA, protecting both the battery and preventing overheating of the voltage regulator.
- Battery charging is maintained at two different, constant-voltage levels, nominally 14.4 volts and 13.8 volts, depending on the use and condition of the battery.
- Battery charging is temperature compensated, -4mV/degree C/cell.

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3.6 SPM-1 LED Board

The 7-segment LED display consists of a green, 3-digit, common cathode component. Digit height is 0.56”. Axial intensity matching of individual digit segments is optimised due to the integration of all three digits in a single package. Individual LED’s provide status indicators for the ALARM LIMIT SET MODE, CAL STEP MODE, and HIGH ICP ALARM.

Commands are written to the LED Board from the Digital Board. A single IC on the LED Board performs all of the LED decoding and multiplexing, freeing the SPM-1 microprocessor from these tasks.

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4.1 Introduction

The following tests provide verification that the SPM-1 is in good operating condition and provides accurate results.

These tests can be performed in any order and individual tests may be selected for performance from the entire series of tests. None of these operational testing procedures require disassembly of the SPM-1.

If any performance parameter is not met, or an obvious malfunction occurs, the SPM-1 should be returned to Integra NeuroSciences for service.

Table 4-1 Recommended Tools and Test Equipment

Equipment Description		Notes	Quantity
Resistor, 620Ω, 5%, ¼ Watt, or equivalent			1
DC Power Supply, BK Model 1610, or equivalent		0-9VDC minimum	1
Digital Multimeter, HP Model 34401A, or equivalent		.001 mV minimum reading	1
Safety Analyser, Dale Model 600E, or equivalent			1
Cables	Power Cord, Integra P/N 60-006 or 60-007, or equivalent		1
	PAC-2 Pre-Amp Cable, Integra P/N PAC-2		1
	PMIO-SPM Cable, Integra P/N PMIO-SPM		1
Pressure Source	Calibrated Pressure Source, Druck Model DPI 610, or equivalent	0 – 125 mmHg (minimum)	1
	Pressure Gauge, Wallace & Tiernan Model 62A-5B-0030 D, or equivalent	0 – 125 mmHg (minimum)	1
	Syringe		1
	Tubing, Silicone, or equivalent		2ft
	Male Luer, or equivalent		1
	3-way stopcock with Luer Lock, or equivalent		1
Catheter, Integra 110-4 Series		See Sec.1.7 for P/N's	1

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Figure 4-1
Blinking CCC Message

Figure 4-2
Catheter Connects to Preamp

4.2 Power On Self Test (POST)

The SPM-1 performs a variety of internal tests when it is initially turned on. Successful completion of the POST ensures that major portions of the system are operating correctly.

Without a Preamp Cable connected to the SPM-1, press the START/STOP button on the front panel. Ensure the following:

- Verify an audible tone sounds and that the LED DISPLAY momentarily indicates 888.
- Verify status LED's "HIGH ICP ALARM", "ALARM LIMIT SET MODE", and "CAL STEP MODE" light up for approximately 1 second.
- Verify the system momentarily displays the software version, followed by the blinking Check Catheter Connection message "CCC" (Figure 4-1).

4.3 Data Update Verification

1. Connect the Preamp Cable to the SPM-1. Attach a catheter to the Preamp Cable (Figure 4-2).
2. After a short system test a pressure reading will be displayed. Ensure a blinking dot is present in the lower right corner of the display.

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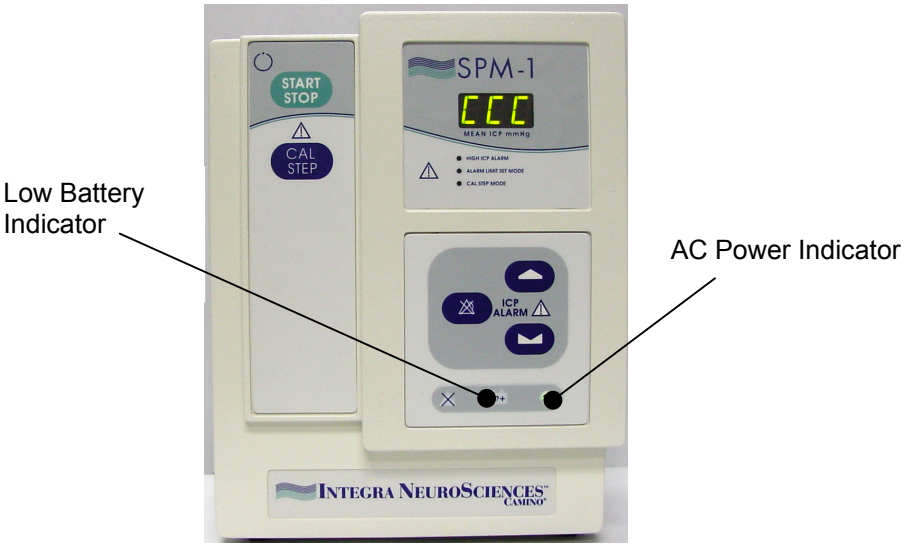

Figure 4-3
AC Power Indicator and Low Battery Indicator

4.4 AC Power Indicator Verification

1. Turn on the SPM-1 by pressing the START/STOP button. Connect the Preamp Cable to the SPM-1. Connect a catheter to the Preamp Cable. After a short system test, a pressure reading will be displayed.
2. Connect one end of the AC power cord into the AC CONNECTOR on the back of the SPM-1. Connect the other end of the AC power cord to an AC outlet.
3. Check that the AC POWER INDICATOR is illuminated (Figure 4-3).
4. Disconnect the power cord. Check that the AC POWER INDICATOR turns off.

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4.5 Battery Charge, Capacity, and Low Battery Indicator Verification

1. Ensure the battery has been fully discharged by operating the SPM-1 on battery power until it automatically turns off.
2. Connect the AC power cord to the SPM-1 AC CONNECTOR. Connect the other end of the power cord to an AC outlet. Verify the SPM-1 AC POWER INDICATOR is illuminated.
3. With the SPM-1 turned off, allow 8-10 hours for the battery to recharge.
4. Disconnect the power cord from the SPM-1. The SPM-1 must be operating from battery power for the following test.
5. Connect a Preamp Cable and catheter to the system. Turn the unit on. Verify an ICP value is displayed and the blinking dot is present in the lower right corner of the display.
6. Let the unit run on battery power until the LOW BATTERY INDICATOR illuminates. At least 2 hours of operational time should be available before the LOW BATTERY INDICATOR becomes illuminated. A new, fully charged battery may take up to 5 hours to discharge.
7. Ensure the LOW BATTERY INDICATOR illuminates at least 15 minutes before the SPM-1 automatically turns off.

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4.6 Battery Charging Voltage Levels

The following procedure may be performed if the SPM-1 fails to operate on battery power for at least 2 hours as described in section 4.5. This procedure provides verification that the battery charge voltage levels are at the proper levels for charging the battery.

1. Turn off the SPM-1 and disconnect its power cord from the AC outlet. Disconnect the spade lug connectors from the SPM-1 battery (refer to section 4.7, “Battery Replacement”).
2. Connect the power cord to the AC outlet and the SPM-1. Measure the voltage across the battery spade lug connectors (Figure 4-4). At room temperature (20°C, 68°F) the voltage will read approximately 13.8 VDC.

Note: If room temperature is warmer, the voltage will be lower.
If room temperature is cooler, the voltage will be higher.

3. Disconnect the power cord from the AC outlet. Connect a 620Ω resistor to the spade lug connectors (Figure 4-5). Connect the power cord to the AC outlet. Measure the voltage across the resistor. At room temperature (20°C, 68°F), voltage will read approximately 14.4 VDC.

Note: If room temperature is warmer, the voltage will be lower.
If room temperature is cooler, the voltage will be higher.

4. If approximately 13.8VDC and 14.4VDC are measured, the charger is working properly. Observing proper polarity, reinstall the SPM-1 battery. Charge the battery for a minimum of 8-10 hours as described in section 4.5.
5. If battery fails to operate the SPM-1 for a minimum of 2 hours after being charged, and approximately 13.8VDC and 14.4VDC are measured, replace battery per section 4.7 or return system for new battery replacement.

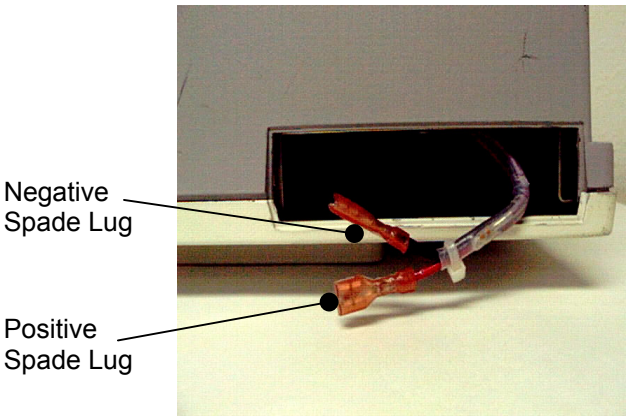

Figure 4-4
Battery Spade Lug Connectors

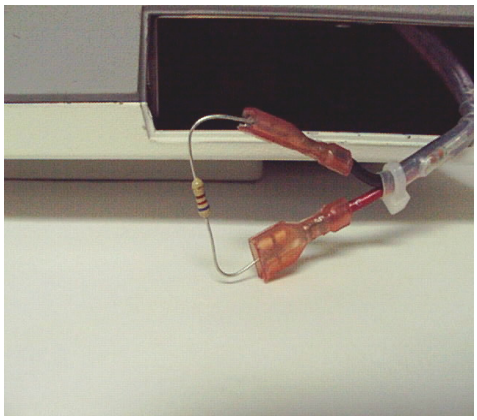

Figure 4-5
Spade Lugs with 620Ω Resistor

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4.7 Battery Replacement

Caution Ensure that the unit is turned off and the power cord has been removed from the unit before attempting this procedure.

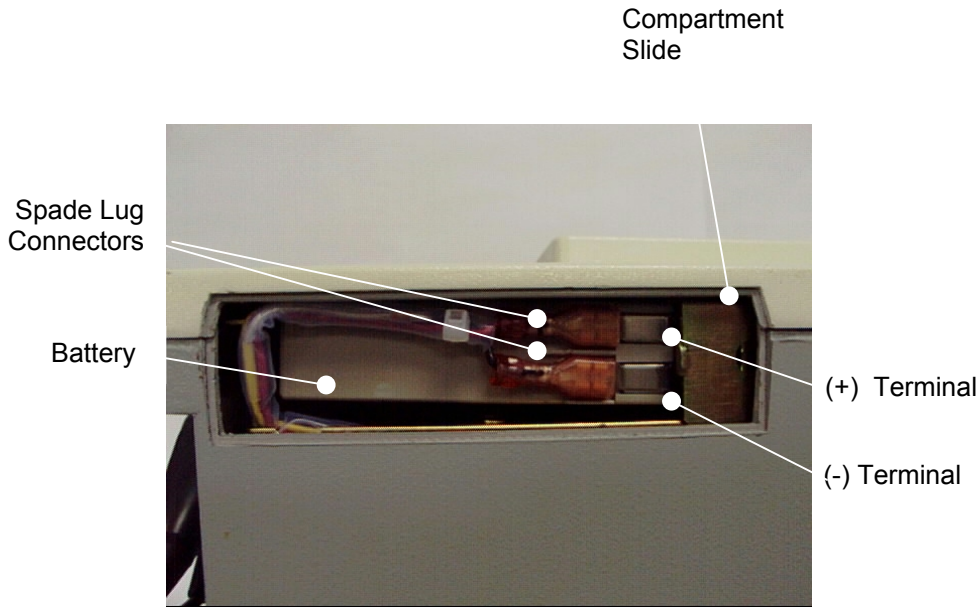

Figure 4-6
Battery Compartment

1. Using a flat bladed screwdriver, carefully lift off the battery compartment door by inserting the screwdriver into the battery compartment notch and twisting.
2. Move the metal battery compartment slide in the direction indicated to open.
3. Remove the spade lug connectors (Figure 4-6) from the positive and negative terminals.
4. Gently slide the battery out of the battery compartment.
5. Replace the battery in the battery compartment.
6. While observing polarity, reconnect the spade lug connectors to the battery terminals. The “+” wire to the positive terminal and the “-” wire to the negative terminal. Ensure that the black side of the battery is on the right side, as shown in Figure 4-6
7. Move the metal battery compartment slide in the direction indicated until it is closed.
8. Replace the battery compartment door and snap into place.
9. Dispose of old battery properly per applicable and local regulations.

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Figure 4-7
Cal Step Button and Mode Indicator

4.8 Cal Step Button and Cal Step Mode Indicator Verification

1. Turn on the SPM-1 by pressing the START/STOP button. Connect the Preamp Cable to the SPM-1. Attach a catheter to the Preamp Cable. The SPM-1 will display a pressure reading.
2. Press and release the CAL STEP BUTTON (Figure 4-7). Verify the CAL STEP MODE INDICATOR becomes illuminated and the SPM-1 displays 0 mmHg for approximately 5 seconds, and then returns to normal pressure display.
3. Continually press and release the CAL STEP BUTTON. Verify the CAL STEP MODE INDICATOR becomes illuminated and each press advances the SPM-1 display to the next pressure value in the following series: 0, 20, 40, 100, 125, and back to 0.

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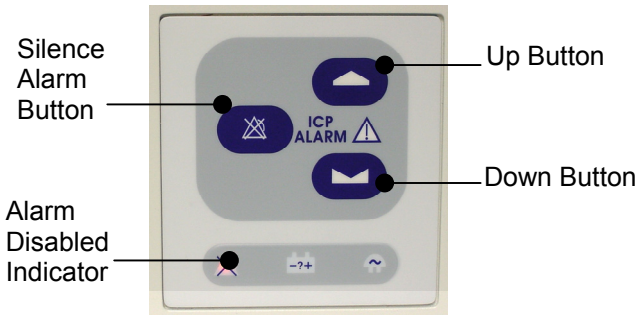

Figure 4-8
Buttons and Indicators

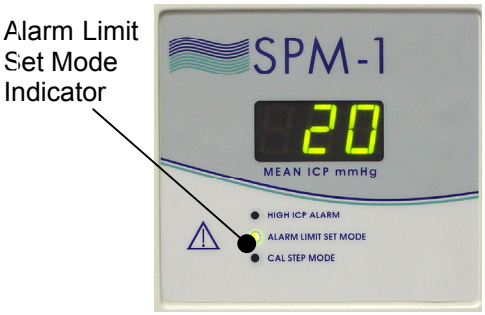

Figure 4-9
Alarm Limit Set Mode Indicator

4.9 Up, Down Button and Alarm Limit Set Mode Indicator Verification

1. Turn on the SPM-1 by pressing the START/STOP button. Connect the Preamp Cable to the SPM-1. Attach a catheter to the Preamp Cable. The SPM-1 will display a pressure reading.
2. Press and release the UP BUTTON or DOWN BUTTON (Figure 4-8). Verify the SPM-1 ALARM LIMIT SET MODE INDICATOR becomes illuminated (Figure 4-9). Within 5 seconds the SPM-1 will return to normal pressure display and the ALARM LIMIT SET MODE INDICATOR will turn off.
3. Continually press the UP and DOWN BUTTON in order to select alarm limit settings between 1 to 75 mmHg, and OFF.

4.10 Alarm Disabled Indicator Verification

1. Turn on the SPM-1 by pressing the START/STOP button. Connect the Preamp Cable to the SPM-1. Attach a catheter to the Preamp Cable. The SPM-1 will display a pressure reading.
2. Press the UP or DOWN BUTTON to obtain an alarm limit setting between 10 and 20 mmHg. Verify the ALARM DISABLED INDICATOR is not illuminated.
3. Press the DOWN BUTTON to adjust the alarm limit setting to OFF. Verify the ALARM DISABLED INDICATOR is continually illuminated.

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4.11 High ICP Alarm Indicator and Audible Alarm Verification

1. Turn on the SPM-1 by pressing the START/STOP button. Connect the Preamp Cable to the SPM-1. Attach a catheter to the Preamp Cable. The SPM-1 will display a pressure reading.
2. Press the UP or DOWN BUTTONS to obtain an alarm limit setting of 10 mmHg.
3. Use the zero adjust tool from a Catheter Kit to turn the zero adjustment (Figure 4-10) on the bottom side of the catheter connector until the displayed ICP is 11 mmHg or greater.
4. Verify the following:
    - An audible alarm is initiated
    - The red HIGH ICP ALARM INDICATOR is continually illuminated
    - The displayed ICP value blinks
5. Press the SILENCE ALARM BUTTON. Verify the audible alarm is silenced and the ALARM DISABLED INDICATOR blinks. Verify the red HIGH ICP ALARM INDICATOR remains illuminated and the displayed ICP value continues to blink.
6. Verify after 3 minutes have elapsed that the audible alarm turns back on and the ALARM DISABLED INDICATOR turns off.
7. Readjust the zero adjustment on the catheter connector to obtain a displayed ICP of 0 mmHg.
8. Press the DOWN button and reset the alarm to OFF.

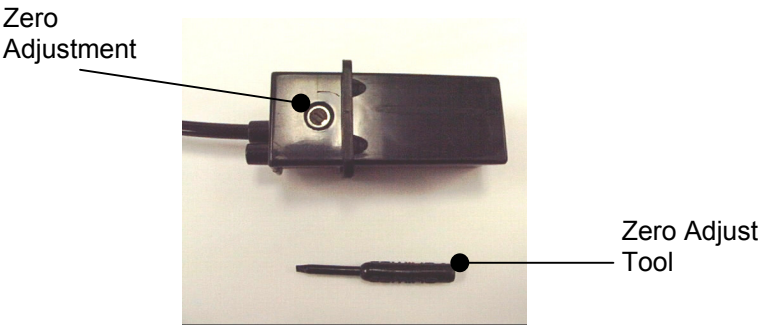

Figure 4-10
Zero Adjustment

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4.12 ICP Input Verification

The following tests provide verification that the overall system is accurately measuring pressure values throughout the entire dynamic range of the SPM-1. Several methods exist to accomplish this. The desired method is dependent upon the test equipment available and the tester's familiarity with the test equipment. Note that methods 1 and 2 require pulling a vacuum on the catheter vent tube while methods 3 and 4 require the application of positive pressure on the catheter tip.

4.12.1 ICP Input Verification Method 1
Catheter Vent Tube and Calibrated Pressure Source

This test places a known pressure from a calibrated pressure source on the SPM-1 catheter's vent tube. The pressure source must be capable of applying negative pressure (vacuum) to the vent tube. The known pressure source readings are compared to the SPM-1 measurements.

1. Turn on the SPM-1. Connect the Preamp Cable to the SPM-1. Attach a functional catheter to the Preamp Cable. The SPM-1 will display a pressure reading. If necessary, adjust the zero adjustment on the catheter to obtain 0 mmHg.
2. Connect one end of a line of silicone tubing to the catheter vent tube (Figure 4-11). Ensure the connection is airtight. Connect the other end of the silicone tubing to a calibrated pressure source capable of pulling vacuum such as the Druck DPI 610 (Figure 4-12) or Utah Medical Delta-Cal.
3. Ensure the pressure source and SPM-1 both indicate 0 mmHg before proceeding. If necessary, adjust the zero adjustment on the catheter to obtain 0 mmHg.
4. Adjust the pressure source to the opposite (negative) value of those indicated in Table 4-2 column "Applied Pressure". Allow adequate time for the SPM-1 reading to settle. Verify the SPM-1 reading is within the limits indicated in Table 4-2.

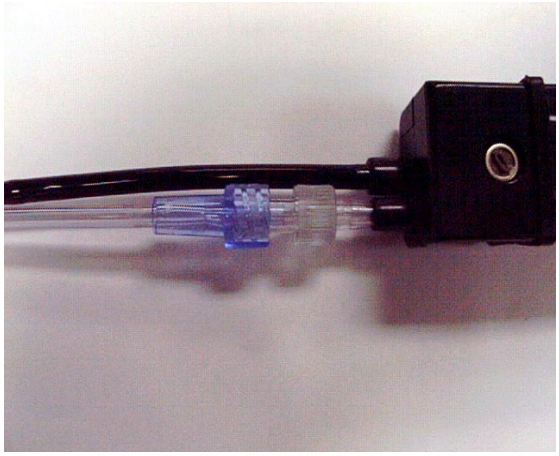

Figure 4-11
Silicone Tubing Connected to
Catheter Vent Tube

Figure 4-12
Druck Pressure Source Connected to Catheter Vent Tube

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4.12.2 ICP Input Verification Method 2

Catheter Vent Tube and Calibrated Pressure Gauge

This test places negative pressure (vacuum) on the SPM-1 catheter vent tube by pulling on a syringe plunger. The pressure is coupled to the SPM-1 and a calibrated pressure gauge by a 3-way stopcock. The measurement obtained from the pressure gauge is compared to the measurement made by the SPM-1.

1. Turn on the SPM-1. Connect the Preamp Cable to the SPM-1. Attach a functional catheter to the Preamp Cable. The SPM-1 will display a pressure reading. If necessary, adjust the zero adjustment on the catheter to obtain 0 mmHg.
2. Connect one end of a line of silicone tubing to the catheter vent tube (Figure 4-11). If needed, use a male luer to ensure the connection is airtight. Connect the other end of the silicone tubing to a 3-way stopcock (Figure 4-13).
3. Connect a second line of silicone tubing between the 3-way stopcock and a calibrated pressure gauge with a vacuum range up to 125 mmHg, such as the Wallace Tiernan Model 62A-5B-0030 D, or equivalent (Figure 4-14).
4. Connect a syringe to the 3-way stopcock. The silicone tubing should provide an airtight connection between the syringe, catheter vent tube, and the pressure gauge.
5. Ensure the pressure gauge and SPM-1 both indicate 0 mmHg before proceeding. If necessary, adjust the zero adjustment on the catheter to obtain 0 mmHg.
6. Pull on the syringe's plunger to apply the opposite (negative) value of those indicated in Table 4-2 column "Applied Pressure". Allow adequate time for the SPM-1 reading to settle. Verify the SPM-1 reading is within the limits indicated in Table 4-2.

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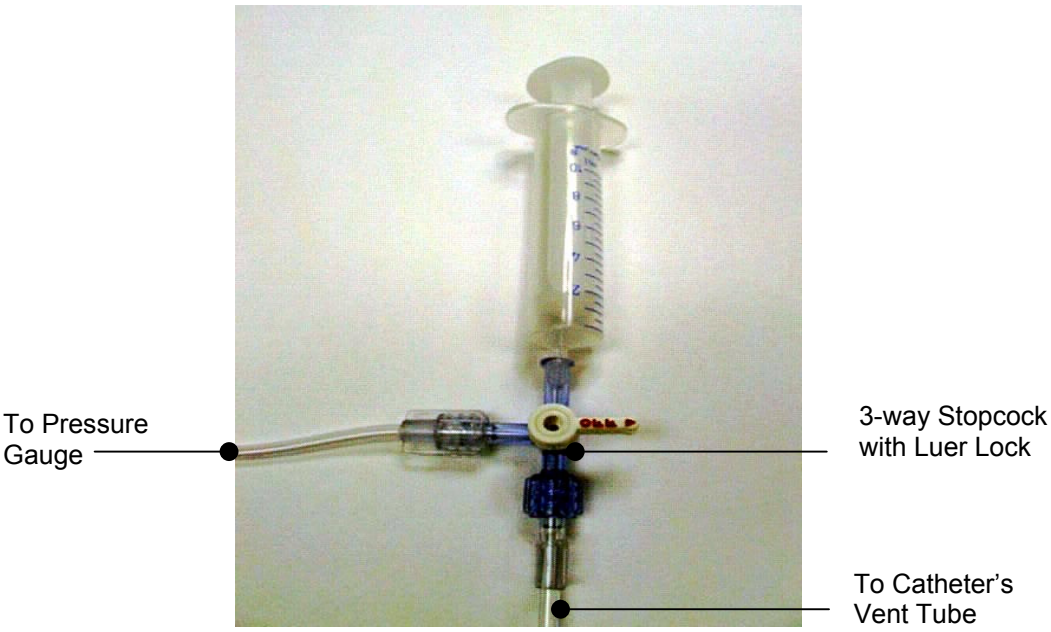

Figure 4-13
Syringe Connection

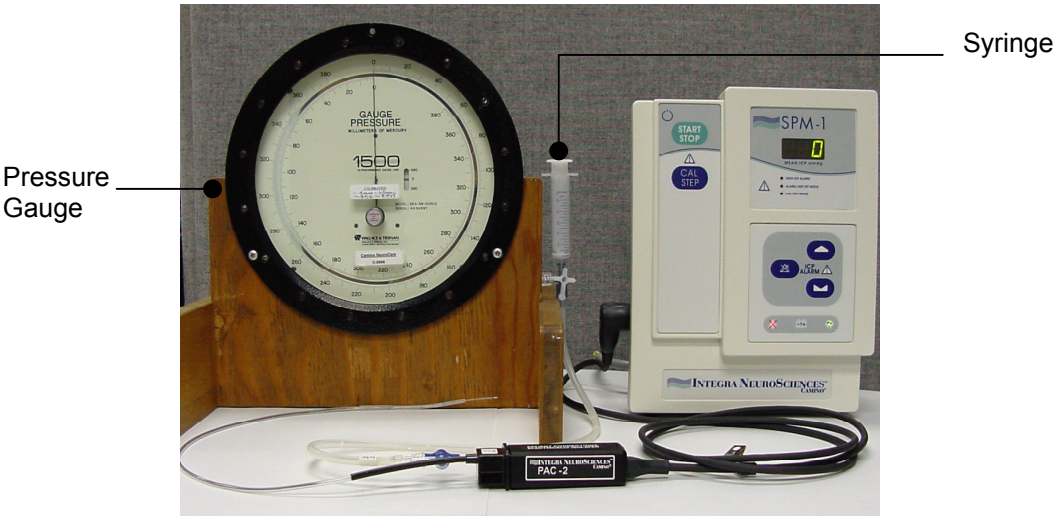

Figure 4-14
Catheter Vent Tube and
Calibrated Pressure
Gauge Setup

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4.12.3 ICP Input Verification Method 3
Catheter Tip and Calibrated Pressure Source

This test places a known pressure from a calibrated pressure source on the SPM-1 catheter's tip. The known pressure source readings are compared to the SPM-1 measurements.

1. Turn on the SPM-1 by pressing the START/STOP button. Connect the Preamp Cable to the SPM-1. Attach a functional catheter to the Preamp Cable. The SPM-1 will display a pressure reading.
2. Ensure the SPM-1 display indicates an ICP pressure of 0 mmHg. If not, use the zero adjust tool from the Catheter Kit to turn the zero adjustment on the bottom side of the catheter connector.
3. Connect one end of a line of silicone tubing to the catheter tip. Ensure the connection is airtight. Connect the other end of the silicone tubing to a calibrated pressure source such as the Druck DPI 610 or Utah Medical Delta-Cal.
4. Ensure the pressure source and SPM-1 both indicate 0 mmHg before proceeding. If necessary, adjust the zero adjustment on the catheter to obtain 0 mmHg.
5. Adjust the pressure source to the values indicated in Table 4-2 column "Applied Pressure". Allow adequate time for the SPM-1 reading to settle. Verify the SPM-1 reading is within the limits indicated in Table 4-2.

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4.12.4 ICP Input Verification Method 4
Catheter Tip and Calibrated Pressure Gauge

This test places pressure on the SPM-1 catheter's tip by pressing down a syringe plunger. The pressure is coupled to a calibrated pressure gauge by a 3-way stopcock. The measurements obtained from the pressure gauge are compared to the measurements made by the SPM-1.

1. Turn on the SPM-1 by pressing the START/STOP button. Connect the Preamp Cable to the SPM-1. Attach a functional catheter to the Preamp Cable. The SPM-1 will display a pressure reading.
2. Ensure the SPM-1 display indicates an ICP pressure of 0 mmHg. If not, use the zero adjust tool from the Catheter Kit to turn the zero adjustment on the bottom side of the catheter connector.
3. Connect one end of a line of silicone tubing to the catheter tip. Ensure the connection is airtight. Connect the other end of the silicone tubing to a 3-way stopcock (Figure 4-13).
4. Connect a second line of silicone tubing between the 3-way stopcock and a calibrated pressure gauge, such as the Wallace Tiernan Model 62A-5B-0030 D, or equivalent.
5. Connect a syringe to the 3-way stopcock. The silicone tubing should provide an airtight connection between the syringe, catheter tip, and the pressure gauge.
6. Ensure the pressure gauge and SPM-1 both indicate 0 mmHg before proceeding. If necessary, adjust the zero adjustment on the catheter to obtain 0 mmHg.
7. Press down on the syringe's plunger to obtain the "Applied Pressure" values indicated in Table 4-2. Allow adequate time for the SPM-1 reading to settle. Verify the SPM-1 reading is within the limits indicated in Table 4-2.

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4.12.5 ICP Input Verification Method 5
Graduated Drainage Bag

This test uses a fluid filled graduated drainage bag to place pressure on the catheter tip. As the height of the bag is adjusted the response of the system is observed.

1. Turn on the SPM-1 by pressing the START/STOP button. Connect the Preamp Cable to the SPM-1. Attach a functional catheter to the Preamp Cable. The SPM-1 will display a pressure reading.
2. Prepare a fluid filled IV bag with tubing and fittings that place the fluid on the catheter tip. Ensure there are no bubbles in the fluid column that connects the IV bag and catheter tip. The connection should be leak free.
3. Align the surface of the fluid in the IV bag to the catheter tip, so that they are at the same height. Adjust the zero adjustment on the catheter to obtain 0 mmHg.
4. Raise the IV bag to various heights while maintaining the original position of the catheter. The difference in height between the surface of the fluid in the IV bag and the catheter tip will cause a pressure difference of 1.87 mmHg / inch (0.74mm hg/cm).
5. Raise the IV bag 10.7” above its original position. The SPM-1 should indicate 20 mmHg $\pm$ 2 mmHg, as indicated in Table 4-2. Adjust the height of the IV bag as desired to obtain additional readings.

Table 4-2 Acceptable Range of Pressure

Applied Pressure	SPM-1 Reading
0 mmHg	0 mmHg
20 mmHg	18 to 22 mmHg
40 mmHg	38 to 42 mmHg
60 mmHg	56 to 64 mmHg
100 mmHg	94 to 106 mmHg
115 mmHg	108 to 122 mmHg

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4.13 Patient Monitor Output Verification

These tests provide verification that the SPM-1 patient monitor output is operating properly. Method 1 uses a patient monitor to accomplish this. If a patient monitor is not available method 2 may be used.

4.13.1 Patient Monitor Output Verification Method 1

Direct Connection to the Patient Monitor

1. Turn on the SPM-1 by pressing the START/STOP button, Connect the Preamp Cable to the SPM-1. Attach a functional catheter to the Preamp Cable. The SPM-1 will display a pressure reading. Connect the PMIO-SPM cable to the PATIENT MONITOR CONNECTOR at the rear of the unit. Connect the required ADAPTOR CABLE to the PMIO-SPM cable and connect to the patient monitor.
2. Press the CAL STEP BUTTON repeatedly until 0 mmHg is displayed on the SPM-1.

Note: The CAL STEP momentarily interrupts normal pressure display on both the SPM-1 and the external patient monitor. The CAL STEP MODE INDICATOR is illuminated while in this mode.

3. While keeping the button depressed to maintain 0, simultaneously zero the bedside monitor.
4. After properly zeroing the bedside monitor press the **CAL STEP** button to advance to the next mmHg value in the following series: 0, 20, 40, 100, 125 and back to 0. Verify the bedside monitor reading at each step.
5. Release the CAL STEP BUTTON. Within a few seconds, the SPM-1 will return to the normal pressure display.

Note: The CAL STEP BUTTON may be used at any time, and does not affect the transducer calibration.

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4.13.2 Patient Output Verification Method 2
Using Digital Voltmeter and Power Supply

1. Turn on the SPM-1 by pressing the START/STOP button. Connect the Preamp Cable to the SPM-1. Attach a functional catheter to the Preamp Cable. The SPM-1 will display a pressure reading.
2. Connect a PMIO-SPM cable to the PATIENT MONITOR CONNECTOR on the rear of SPM-1, but do not connect to an external bedside monitor.

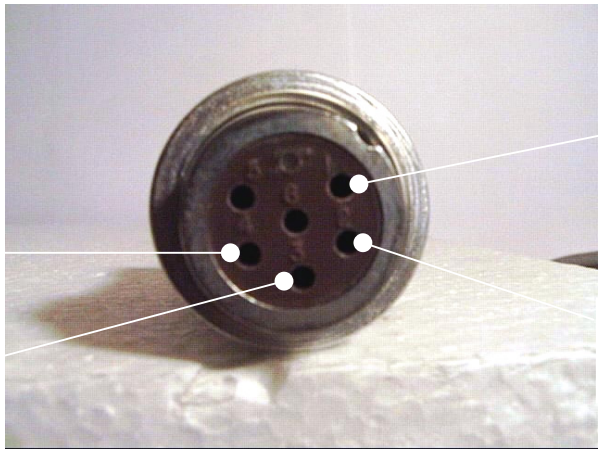

Figure 4-15
PMIO-SPM Connector

3. Set the power supply to 5.000 ± 0.001 volts. Connect the positive output to “PIN 1: PS+”. Connect the negative output to “PIN 4: PS-” of the PMIO-SPM Cable connector (Figure 4-15).
4. Connect the “+” and “-” leads of the Digital Multimeter (DMM) to pins “PIN 2: DMM+” and “PIN 3: DMM-” of the connector, respectively.
5. Press and hold the CAL STEP BUTTON to produce 0 mmHg on the display. The DMM should read less than .010 mVDC offset from 0 volts. This offset must be subtracted from the following measurements. If the DMM provides an offset feature select it to automatically subtract this offset from following measurements. If not, mentally subtract this value from the following measurements.
6. Press the SPM-1 CAL STEP BUTTON to obtain the Cal Step Value indicated in table 4-3. Verify the measured PMIO Output Voltage in Table 4-2 is within the limits indicated.
7. Turn off the SPM-1. Remove power supply and DMM leads from PMIO cable connector.

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Table 4-3 CAL STEP Values and PMIO Output Voltage

Cal Step Value(mmHg)	PMIO Output Voltage
0	0.000 ± .001 mVDC
20	0.500 ± .001 mVDC
40	1.000 ± .001 mVDC
100	2.500 ± .001 mVDC
125	3.125 ± .001 mVDC

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5.1 Introduction

The SPM-1 safety classification is Class I Type BF. Protection against electric shock is achieved by use of insulation and a protectively grounded enclosure. The SPM-1 monitor is interfaced to the patient via the preamp cable and disposable catheter. The type BF connection to the patient is accomplished with a catheter that is constructed of non-conductive glass optic fibres. Therefore, there is no electrical connection between the SPM-1 monitor and patient.

Safety tests are designed to provide verification of meeting relevant medical device regulatory requirements and ensuring that there is no danger of electrical shock associated with the system. All SPM-1 systems are safety tested prior to shipment and during routine maintenance and service repair.

Safety tests performed incorrectly or inappropriately may result in damage to the SPM-1. Only trained personnel should perform these tests. It is suggested that bioengineering departments utilise the following information in a manner that is consistent with their policies.

5.2 Ground Bond Integrity Test

Leakage current that flows inside of a Class I device is carried to earth through the protective earth conductor. This current cannot present a hazard as long as the conductor remains intact and the current does not become too large. If this occurs the enclosure potential could rise relative to earth ground. The Ground Bond Integrity Test verifies the reliability of the protective earth conductor under the extreme fault condition of 25 Amps. This test is compliant with IEC601-1 and UL2601-1 requirements.

1. Connect one lead of the ground bond tester to the ground pin of the SPM-1 AC CONNECTOR.
2. Connect the ground bond tester's other lead to the EQUIPOTENTIAL LUG on the rear of the SPM-1.
3. Apply 6VAC, 25 Amps for 5 seconds. Verify the ground bond tester measures less than 0.1Ω.
4. If the power cord supplied with the SPM-1 is used as part of test circuit the ground bond tester should measure less than 0.2Ω.

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5.3 Earth Leakage Current Test

This is the current that normally flows in the protective earth conductor of a Class I device. This current cannot present a hazard as long as the protective earth conductor wire remains intact and the current does not become too large. If this occurs the enclosure potential could rise relative to earth ground. The Earth Leakage Current Test provides verification that the amplitude of this current is within the requirements specified by the relevant medical regulatory agencies. This test is compliant with IEC601-1 and UL2601-1 requirements.

1. Power the safety analyser with 110% of the normal mains voltage (264 VAC for a normal 240 VAC mains, 132 VAC for domestic units).
2. Connect the SPM-1 power cord to the safety analyser as recommended by the safety analyser operating instructions.
3. Turn the SPM-1 on. Adjust the safety analyser dial to perform earth leakage measurements. Adjust the safety analyser buttons as indicated in Table 5-1.

Table 5-1 Earth Leakage Current

AC Polarity Switch	Neutral Connection	Maximum Allowable Leakage Current
Normal	Closed	500uA
Reversed	Closed	500uA
Normal	Open	1000uA
Reversed	Open	1000uA

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5.4 Enclosure Leakage Current

Enclosure leakage current is the current that flows from the enclosure to earth (ground) as measured through the coil cord of the safety analyser. In a Class I medical device with an intact ground this current is very low due to the low resistance (mΩ) parallel path of the protective earth conductor. In a Class I medical device with a disrupted ground (Single Fault Condition) this current will be similar to the value obtained for Earth Leakage Current. This test is compliant with IEC601-1 and UL2601-1 requirements.

1. Power the safety analyser with 110% of the normal mains voltage (264 VAC for a normal 240 VAC mains, 132 VAC for domestic units).
2. Connect the SPM-1 power cord to the safety analyser as recommended by the safety analyser operating instructions. Connect the safety analyser coil cord to the EQUIPOTENTIAL LUG of the SPM-1.
3. Turn the SPM-1 on. Adjust the safety analyser dial to perform enclosure leakage current measurements. Adjust the safety analyser buttons as indicated in Table 5-2.

Table 5-2 Enclosure Leakage Current

AC Polarity Switch	Neutral Connection	Ground Connection	Maximum Allowable Current
Normal	Closed	Closed	100uA
Normal	Closed	Open	500uA
Normal	Open	Closed	500uA
Reversed	Closed	Closed	100uA
Reversed	Closed	Open	500uA
Reversed	Open	Closed	500uA

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5.5 Lead to Ground (Patient Source) Leakage Current

This is the current that could flow from the device, through the patient, and to earth ground if patient were to come into contact with earth ground. Since there is no electrical connection between the SPM-1 and the applied part (catheter tip) this current is very small. This test is compliant with IEC601-1 and UL2601-1 requirements.

1. The catheter should be connected to the PAC-2 Cable and the PAC-2 Cable should be connected to the SPM-1.
2. Wrap 1” of metal foil around the distal tip of the catheter.
3. Power the safety analyser with 110% of the normal mains voltage (264 VAC for a normal 240 VAC mains, 132 VAC for 110 VAC mains).
4. Connect the SPM-1 power cord to the safety analyser as recommended by the safety analyser operating instructions.
5. Connect the safety analyser patient lead to the metal foil on the distal tip of the catheter. Adjust the safety analyser to measure patient leakage current through the selected patient lead.
6. Turn the SPM-1 on. Adjust the safety analyser buttons as indicated in Table 5-3.

Table 5-3 Lead to Ground (Patient Source) Leakage Current

AC Polarity Switch	Neutral Switch	Ground Switch	Maximum Allowable Current
Normal	Closed	Closed	100uA
Normal	Closed	Open	500uA
Normal	Open	Closed	500uA
Reverse	Closed	Closed	100uA
Reverse	Closed	Open	500uA
Reverse	Open	Closed	500uA

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5.6 Lead Isolation (Mains on Applied Part) Leakage Current

This is the current that could flow through the patient, into the device, and to earth ground if the patient were to come into contact with mains voltage. This test places 110% of mains voltage on the safety analyser test leads and patient connection. Since there is no electrical connection between the SPM-1 and the applied part (catheter tip) this current will be very small. This test is compliant with IEC601-1 and UL2601-1 requirements.

Caution Mains voltage is present on the safety analyser test leads during this test.

1. The catheter should be connected to the PAC-2 Cable and the PAC-2 Cable should be connected to the SPM-1.
2. Wrap 1” of metal foil around the distal tip of the catheter.
3. Power the safety analyser with 110% of the normal mains voltage (264 VAC for a normal 240 VAC mains, 132 VAC for 110 VAC mains).
4. Connect the SPM-1 power cord to the safety analyser as recommended by the safety analyser operating instructions.
5. Connect the safety analyser patient lead to the metal foil on the distal tip of the catheter. Adjust the safety analyser to measure lead isolation patient leakage current through the selected patient lead.
6. Turn the SPM-1 on. Leave the neutral and ground buttons closed for this test. Press the ISO button as indicated in Table 5-4.

Table 5-4 Lead Isolation (Mains on Applied Part) Leakage Current

AC Polarity Switch	Neutral Switch	Ground Switch	ISO Button	Maximum Allowable Current
Normal	Closed	Closed	Press	5mA
Reversed	Closed	Closed	Press	5mA

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6.1 Introduction

The troubleshooting guide is intended to resolve problems that may occur while using the SPM-1. This section contains troubleshooting isolation tables. If the difficulty persists after attempting to troubleshoot, or if a problem other than those described below occurs, routine technical assistance may be obtained by contacting Integra NeuroSciences.

Note: If it is necessary to return the SPM-1 monitor or catheter to Integra NeuroSciences, please provide a detailed description of the problem and any errors that were shown. This will assist in the proper servicing of your equipment. Please call Integra NeuroSciences for specific instructions on returned goods procedures.

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6.2 Power Supply Malfunctions

Symptom	Possible Cause	Corrective Action
SPM-1 does not operate on AC power, but system works on battery.	AC power cord not connected.	Verify power cord is plugged into a live AC power source.
	Faulty AC power cord.	Replace power cord.
	Blown fuse.	Replace fuse.
	Power module malfunctioning.	Send unit in for service.
SPM-1 does not operate on battery, but system operates on AC power. Or Battery does not charge.	Faulty battery.	Refer to section 4.5 for determination of adequate battery capacity. Send unit in for service.
	Battery terminal wires damaged / reversed.	Send unit in for service.
ON and OFF button does not work properly.	Faulty membrane switch and/or power supply.	Send unit in for service.

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6.3 LED Display Malfunction

Symptom	Possible Cause	Corrective Action
SPM-1 is operating, but no LED Display is present. OR LED Display is missing segments.	Faulty LED Board or LED Board connections.	Send unit in for service.
SPM-1 displays a pressure reading, but no blinking dot is present in the lower right corner of the screen.	Faulty processor communication.	Send unit in for service.
High ICP Alarm indicator, Alarm Limit Set Mode indicator, Cal Step Mode indicator do not illuminate.	Faulty LED Board or LED Board connections.	Send unit in for service.

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6.4 Error Messages

SPM-1 Display	Possible Cause(s)	Corrective Action
"CCC" Check Catheter Connection Message	Appears whenever catheter and preamp are not connected to the SPM-1	Check catheter and preamp connections per section 2.2
	Broken reference fibre in the catheter	Replace catheter
	Faulty preamp cable	Replace preamp cable
	Faulty cable connection internal to the SPM-1	Send unit in for service
	Faulty Analogue Board or Digital Board	Send unit in for service
"- - -" Out-of-range Message	The measured ICP value may be out of the measurable range of –10 mmHg to 125 mmHg due to the position of the zero pot	Before inserting the catheter into the patient, adjust the zero pot per section 2.2
	Broken signal fibre in the catheter	Replace catheter
	Faulty preamp cable	Replace preamp cable
	Faulty Analogue Board or Digital Board	Send unit in for service
	Patient ICP value might be out of measurable range	Assess patient for clinical changes
" - " " - " " - " Dashes moving across the screen, one at a time	Normally appears for less than 10 seconds whenever a new catheter is inserted into a preamp cable or when the system is first turned on	None required
	Dashes continually appear	Send SPM-1 (and catheter) in for service

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6.4 Error Messages (cont.)

“EO1”	Digital Board flash took too long to erase during power on self test	If problem continually occurs send unit in for service
“EO2”	Data transfer between video and pressure processor disrupted	If problem continually occurs send unit in for service
“EO4”	Alarm Silence button stuck or Cal Step button stuck during power on self test	Send unit in for service
“EO6”	Pressure and video PSD versions do not match during power on self test	Send unit in for service
“E13”	Pressure PSD CRC failure during power on self test	Send unit in for service
“E14”	Video PSD CRC failure during power on self test	Send unit in for service
“OFF”	Down button stuck while preamp and catheter connected	Send unit in for service
“75/CAL”	Up button stuck during power on self test while preamp and catheter are connected	Send unit in for service
“CCC/CAL”	Up button stuck during power on self test while catheter is not installed	Send unit in for service
“2.00” and Alarm Limit Set Mode indicator flash for a few seconds during power-up	SPM-1 was turned OFF/ON too quickly causing flash memory contents to reset	Wait for at least 5 seconds between turning the SPM-1 OFF and ON

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6.5 Cabling and Interface Problems

Symptom	Possible Cause	Corrective Action
Discrepancy in pressure reading between the SPM-1 and the patient monitor.	Patient monitor out of calibration.	Re-calibrate or re-zero the patient monitor using the SPM-1 CAL STEP button. Refer to section 4.13 for specific patient monitor tests.
	Incorrect PMIO signal from SPM.	Send unit in for service.
	Incorrect patient monitor adapter cable being used.	Verify correct patient monitor cable is used. Refer to section 1.9
	Faulty PMIO-SPM cable.	Replace PMIO-SPM cable.
No pressure waveform or numerical display on patient monitor, but SPM-1 displays mean pressure.	PMIO-SPM cable or patient monitor adapter cable is loose.	Check cable connections between patient monitor and SPM-1.
	PMIO-SPM cable or monitor adapter cable is faulty.	Replace faulty cable.
	Patient monitor malfunctioning.	Verify proper operation of patient monitor. Refer to section 4.13 for specific patient monitor tests.
	Faulty internal connection between the PMIO-SPM flex cable and Analogue Board.	Send unit in for service.
	Incorrect PMIO signal from SPM.	Send unit in for service.
No RS-232 communication.	Loose cable.	Reconnect cable.
	Faulty cable.	Replace cable.
	Faulty internal connection between Digital Board and RS-232 cable.	Send unit in for service.

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